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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/923,122 | 08/06/2001 | Gilberto Bestetti | 6330.01 | 9725 |
| 7590 12/15/2004 | | | EXAMINER | |
| DAVID E. BRUHN | | | HAYES, MICHAEL J | |
| DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500, 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498 | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| | | | DATE MAILED: 12/15/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | (Applicant/o) | | | |
|---|---|---|--|--|--|--|
| Office Action Summary | | Application No. | Applicant(s) | | | |
| | | 09/923,122 | BESTETTI ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | The MAN INO DATE of this commission and | Michael J. Hayes | 3763 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| THE - Exte after - If the - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. speriod for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)⊠ 2a)□ 3)□ | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| Disposit | ion of Claims | | | | | |
| 5)□ 6)⊠ 7)□ | | | | | | |
| Applicat | ion Papers | | , | | | |
| 10)⊠ | The specification is objected to by the Examine The drawing(s) filed on <u>06 August 2001</u> is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex | a) accepted or b) objected to drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d). | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachmen | nt(s) | | | | | |
| 2) Notice 3) Infor | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by ANDREUSSI (US Patent No. 5,064,417). Andreussi discloses an implantable device having a shaft, upper fin, lower fin and a pocket with a gap between the edges of the fins that is less than a diameter of a cross-sectional diameter of the pocket. Fig. 2 shows the edges of fins 4, 2 to be closer than a diameter (i.e., a line through the center of a shape) of a cross-section of the pocket.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by BENTLEY et al. (US Patent No. 4183357). Bentley discloses an implantable device having a shaft, radial and anchoring fins forming a rounded cross-sectional pocket 51. See fig. 5.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by HARGEST (US Patent No. 3,461,869. Hargest discloses an implantable device having a shaft, radial and anchoring fins with a rounded cross-sectional pocket 24 between them. See figs. 3,7.

Claims 25 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by GIFFORD, III et al. (US Patent No. 5,817,113). Gifford discloses a device having a shaft, radial fin 168,

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637 anchoring fin 167, 636 and a rounded pocket formed by the fins that has a distance between the edges of the fins less than the diameter of the rounded cross-section of the pocket. See figs. 9, 10, 12, 48B.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY as applied to claim 25 above, and further in view of BOKROS (US Patent No. 3783868). Bentley discloses the claimed invention except for a disc-shaped anchoring plate around the shaft with an anchoring fin. Bokros teaches a disc-shaped anchoring plate 26 around a shaft with an anchoring fin 52 protruding therefrom. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bokros in the invention of Bentley in order to provide anchoring structure to prevent unwanted movement of the implantable device.

Claims 21, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over ANDREUSSI as applied to claims 20 and 23 above, and further in view of SLIVENKO (US Patent No. 4,108,173). Andreussi discloses the claimed invention except for an anchoring plate extending from the lower fin that extends away from the skin. Slivenko discloses an anchoring plate 87 attached to the lower fin that extends away from the skin. It would have been obvious to

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one of ordinary skill in the art at the time of the invention to use the teachings of Slivenko in the device of Andreussi to obtain a greater level of stability for the implantable device to prevent the device from becoming dislodged.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY or HARGEST as applied to claim 25 above and further in view of BROEMER (US Patent No. 4,365,356). Bentley and Hargest disclose the claimed invention except for a bio-active material partially coated on the device. Broemer teaches application of a bio-active material on an implantable device to facilitate tissue ingrowth with the device, 2:1-11.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh

10 December 2004

MICHAEL J. HAYES
PRIMARY EXAMINER